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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,039	11/17/2003	Jeffrey W. Seale	38-21(15546)A	1038

27161 7590 04/12/2007

MONSANTO COMPANY
800 N. LINDBERGH BLVD.
ATTENTION: GAIL P. WUELLNER, IP PARALEGAL, (E2NA)
ST. LOUIS, MO 63167

EXAMINER

ZHENG, LI

ART UNIT	PAPER NUMBER
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1638

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/707,039

Applicant(s)

SEALE ET AL.

Examiner

Li Zheng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-15 is/are allowed.
- 6) ☒ Claim(s) 11, 12 and 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>292004/2202004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III, claims 11-20 and plant cells, as well as cancellation of claims 1-10 and 21-24 in the reply filed on 11/14/2006 are acknowledged. As a result, claims 11-20 are pending and examined on the merits.

The requirement is deemed proper and is therefore made FINAL.

Specification

2. The specification is objected to under 37 CFR 1.821(d) as failing to refer to a sequence by use of its sequence identifier preceded by "SEQ ID NO:". The nucleotide sequences in Figure 1 should be identified with SEQ ID NOs:, respectively.

Alternatively, the brief descriptions of those figures on page 14 can be amended to recite the identifiers.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 12 and 20 are rejected under 35 U.S.C. 112, second paragraph, due to an improper Markush terminology.

In claims 12 and 20: the recitation, "selected from the group consisting ofor zucchini plant/plant cell", is improper per MPEP 2173.05 (h). It is suggested to amend the last line by replacing "or" with -- and --.

Further, for claim 12, the recitation, "said plant cell is....zucchini plant" is confusing for equating a cell with a plant. It is suggested to insert – cell – after "zucchini plant".

4. Claims 11, 16-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a bacterial cell or a plant cell as the host, as well as antifungal activities of said antifungal polypeptides against *Fusarium* species and *Verticillium* species, does not reasonably provide enablement for a fungal cell as the host cell, or any other plant pathogenic fungi. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The specification teaches generating fourteen variants of an antifungal protein isolated from a Medicago plant (page 43, lines 11-13). Among those variants, only one of them, AlfAFP1(SEQ ID NO: 4), exhibited a 3-7-fold increase in antifungal activity in vitro against *Fusarium culmorum*. This variant was transformed into and expressed in

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potato and determined to provide resistance to *Verticillium dahliae* (page 43, lines 14-18; page 55, Tables 1-2).

First, claims 11 reads on expressing antifungal protein in fungal cell. The specification does not provide any guidance on how to make/use such transgenic fungal cell that expresses suicidal protein to kill itself.

Further, claims 16-20 are drawn to a transgenic plant that displays increased resistance to all of the plant pathogens or fungi. However, the specification only teaches that the claimed antifungal protein inhibits the growth of *Fusarium culmorum* in vitro and that the transgenic potato expressing the claimed antifungal protein exhibits resistance to *Verticillium dahliae*. Due to significant genetic conservation among *Fusarium* species and *Verticillium* species, it is expected that the claimed antifungal protein is likely to inhibit all of the *Fusarium* species and *Verticillium* species. However, both of these two pathogens belong to ascomycete fungi and can not represent all fungal pathogens. Neither the specification nor the prior art teaches that when expressed in plant, the claimed peptides could confer increased disease resistance to any fungi. Veronese et al. (2003, *Plant Physiology* 131:1580-1590) teach that many plant antimicrobial proteins are toxic to some microbes but are ineffective against others (page 1582, last paragraph). Still further, the mode of action of the claimed antifungal protein is unknown, therefore, it is also unclear if the target of claimed antifungal protein is highly conserved among all the pathogenic fungi. Given the breadth of the claims, lack of guidance on the mode of action of the claimed antifungal peptide, undue experimentation would be required to vigorously test the antifungal activity in vivo and in

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vitro against a significant number of pathogens that could reasonably represent all of the plant pathogens or the whole fungal kingdom.

Given the claim breadth, unpredictability of the art, and lack of further guidance and additional working examples, undue experimentation would be required by one skilled in the art to practice the instant invention in full scope.

Conclusion

Claims 11-12 and 16-20 are rejected. The claims, however, are deemed free of prior art due to the failure of the prior art to teach or fairly suggest the claimed nucleotide sequences encoding the antifungal protein of SEQ ID NO: 4, or plants transformed therewith.

Claims 13-15 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read 'D. Fox', is written below the printed name and title.

